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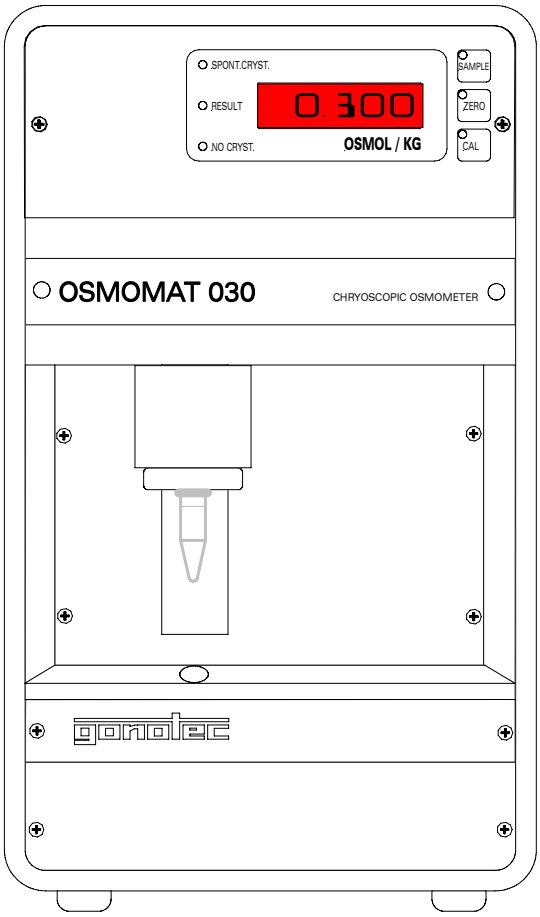
User Guide

Osmolality measurement for the medical and pharmaceutical fields

Cryoscopic Osmometer

OSMOMAT® 030



OSMOMAT® 030 osmometer series ☐ D ☐ RS ☐ M ☐ A ☐ 3P

Notes, Safety Notices and Warnings

The symbols and abbreviations defined below may appear on the packaging material, on the unit nameplate or in the operating instructions:

IVD	In-vitro diagnostic device
CE	This product meets the requirements of EEC Directive 98/79 relating to in-vitro diagnostics.
	Attention (refer to documentation)! Please follow the safety notices in the equipment operating instructions.
	"Use by …" The date that follows indicates the expiration data as *year-month*.
LOT	Appears beside the name of the product batch.
REF	Article number or order number

The following pages provide you with a step-by-step introduction to using, maintaining and servicing the measurement equipment. Passages requiring special attention are marked as follows:

	This symbol warns against the danger of corrupting measurement results—for example, through improper use of measuring vessels.
	This symbol warns against the danger of damaging the unit or the measurement system—for example, through improper servicing.

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OSMOMAT® 030 model, series 1996 and later

May 2006 Version 1.2

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1 Introduction

1.1 Applications of the OSMOMAT 030

The Gonotec cryoscopic osmometer—Osmomat® 030—is a non-invasive in-vitro diagnostic device for in-vitro analysis of human blood, urine, semen and other samples, such as drip solutions. Its purpose is to provide information to help identify, diagnose, monitor and treat physiological conditions, states of health or illnesses.

The OSMOMAT® 030 must be operated by persons whose training or skills have provided them with the necessary practical experience (cf. German Medical Devices Operator Ordinance, *MPBetreibV*).

The cryoscopic osmometer OSMOMAT 030 is particularly suited for routine measurements in the fields of medicine, industry and research. The cryoscopic osmometer OSMOMAT 030 determines the total osmolality of aqueous solutions. Osmolality is an important measure of concentration for diluted solutions, such as all bodily fluids. The OSMOMAT standard model needs a sample volume of 50µl, while the *M* option requires only 15µl, making it suitable for measuring even minute samples. The measuring speed permits rapid series measurements.

In the hospital or doctor's office, osmolality can be used as one of several parameters to help form a diagnosis or prompt further testing. In the pharmaceutical industry and research, the Osmomat 030 is used to test various aqueous solutions (saline drips, etc.) and for process validation.

The OSMOMAT 030 has been applied successfully in the following fields:

General medicine	Urology
Routine and research	Nephrology
Forensic medicine	Hemodialysis
Electron microscopy	Hemofiltration
Physiology	Botany
Clinical laboratories	Veterinary medicine
Intensive care laboratories	Pharmaceutics
Pediatrics	Pharmacies
Gynecology	… and many more

1.1.1 Application Restrictions of the Osmomat 030

- The unit is not intended for determining the osmolality of dilutions.
- Only the osmolality of aqueous solutions can be determined.

Plausibility checks of the results must be performed by the doctor with the support of the pertinent literature.

1.2 Measurement Method of the OSMOMAT 030

The OSMOMAT 030 is a cryoscopic osmometer that measures the freezing point depression to determine the total osmolality of aqueous solutions.
The freezing points of pure water and a solution are measured and compared. Whereas water has a freezing point of 0°C, a solution with a saline concentration of 1 Osmol/kg has a freezing point of –1.858°C. That means that one mol of a given non-dissociated substance (6.023×10^{23} parts diluted in one kilogram of water) lowers the freezing point of a solution by 1.858°C. The following definitions are used in calculating osmolality:

$C_{osm} = \Delta T / K$	C_{osm} = osmolality [osmol/kg] T = freezing point depression [°C] K = 1.858°C kg/osmol freezing point constant

The osmolality indicates the concentration of all osmotically active dissolved parts in the solvent.
Since the freezing point depression is directly proportional to the dissolved parts, the OSMOMAT 030 measures the osmolality directly.

1.3 Reproducibility in the OSMOMAT 030 Standard Model

Measurement display	4.5 digits
Measuring range	0 to approximately 3000 mOsmol/kg
Resolution	1 mOsmol/kg or 1 mOsmol/digit across the entire measuring range
Reproducibility	
Sample volume of 50µl	< ±0.5%
Sample volume of 30µl	< ±1.0%

1.4 Function of the OSMOMAT 030

The sample solution is cooled with a peltier cooling system while its temperature is electronically monitored. Once the sample solution has reached a specific temperature below the freezing point, crystallization is automatically initiated. The OSMOMAT 030 initiates crystallization by injecting the sample with a stainless steel needle that is cooled by a secondary upper cooling system and at the tip of which small ice crystals have formed through moisture in the air. When crystallization begins, ice forms spontaneously. The heat that was removed during undercooling is released again, the temperature rises spontaneously and the temperature of the sample rises to the freezing point.

If the sample consists of water (solvent), equilibrium is achieved as long as the sample contains water and ice. The temperature remains constant because further heat removal does not result in a lowering of the temperature but the formation of ice. The time of temperature equilibrium is known as *plateau time*. Only after complete crystallization the temperature does fall again.

If the sample consists of a solution, the pure water in the solution crystallizes spontaneously and the substances move to the rest of the solution. This means that at the time the freezing point temperature is measured, the concentration is higher than in the original solution. A plateau occurs here as well, but it is inclined. The osmolality reading is taken at the resulting reversal point (Figure 1: **Freezing point depression of solvent**). The temperature is measured with a resolution of 1.858 x 10E-3°C.

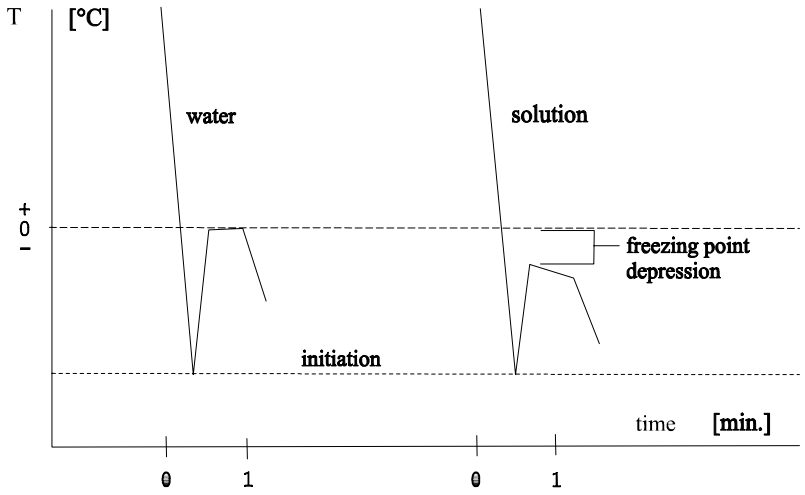


Figure 1: Freezing point depression of solvent

1.5 Unpacking the OSMOMAT 030 Cryoscopic Osmometer

The cryoscopic osmometer OSMOMAT 030 should be unpacked immediately upon receipt and checked for obvious signs of damage sustained during shipping. If any damage is found, notify the manufacturer:

Gonotec GmbH
Eisenacher 56
D-10823 Berlin, Germany

Tel.: +49 (0) 30 7809588-0
Fax: +49 (0) 30 7809588-88
E-mail: contact@gonotec.com
Web: www.gonotec.com

Toll-free service number within Germany: 0800 / 7846027

The packaging for this equipment was specially designed to ensure safe and hygienic transport. The packaging is re-usable. Please save the packaging in case it becomes necessary to ship the unit back to us for repairs or servicing.
This will save you the time and money needed to find equally suitable packaging.

1.6 Packaging Contents

Check to make sure the contents of your shipment is complete. We cannot accept responsibility for any missing items reported at a later date.

Accessories and consumables included in the shipment

	Article number	
OSMOMAT 030	20.9.0100	✓ 1 power cord
	00.9.0104 00.9.0106	✓ 2 fine-wire fuses **230 V 0.5 A** *(for 110 V: 1.0 A)*
	30.9.0010	✓ 100 measuring vessels
	30.9.0020	✓ 20 ampoules calibration standard 300 mOsmol/kg + **certificate**
	30.9.0850	✓ 10 ampoules calibration standard 850 mOsmol/kg + **certificate**
	30.9.0290	✓ 10 ampoules reference solution OSMOREF®290 mOsmol/kg + **certificate**
	30.2.0030	✓ 1 adjustment tool
	30.9.0030	✓ 1 pasteur pipette (bellow)
		✓ 1 user guide 030
Option *D*	30.9.1010	✓ 8 rolls of printer paper
Option R*S*	20.9.0160	✓ 1 RS-232 cable
Option *A*	20.9.0120	✓ 1 analog cable

2 Overview of the OSMOMAT 030

2.1 Overview of Display and Connectors

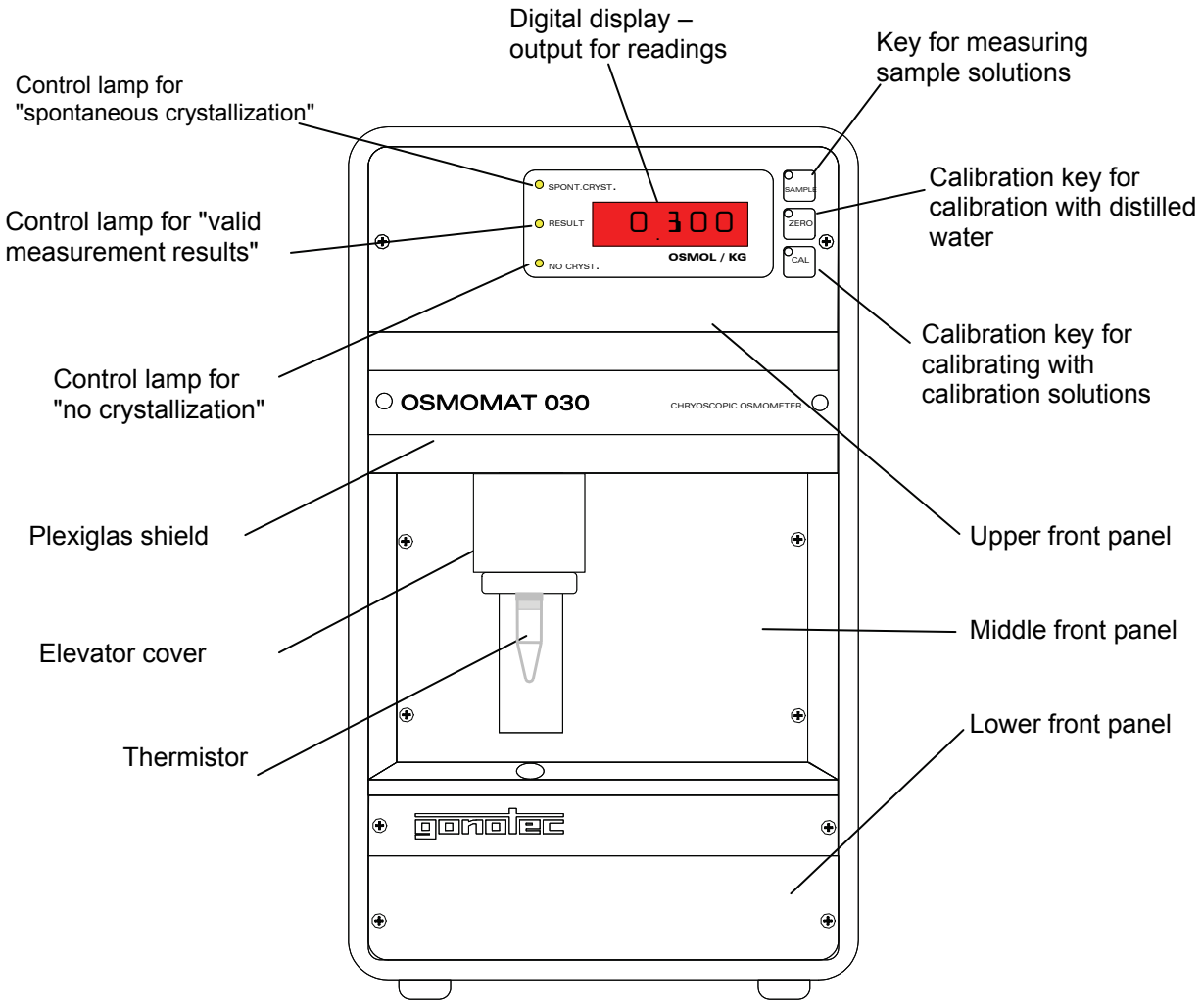


Figure 2: Front view of the OSMOMAT 030

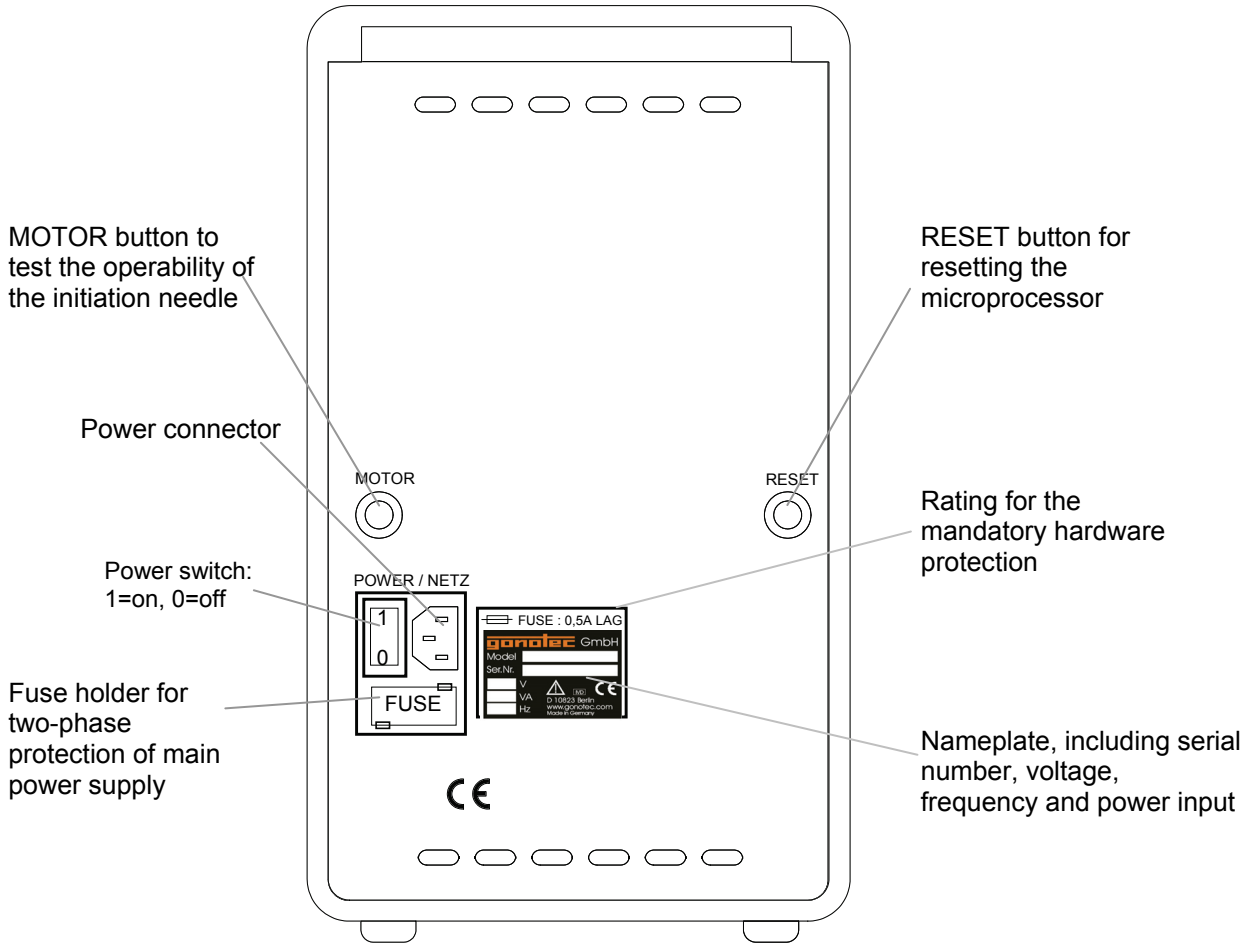


Figure 3: Rear view of the Osmomat 030

2.2 Power Supply

The standard model is supplied with 220V (+/- 30V) at 50/60Hz. The power consumption is 120VA.

Special models using 110V or 100V are also available.

2.3 Dimensions and Weight

Dimensions (width x depth x height): 220x205x360 mm

Weight: approximately 7 kg

3 Setup and Initial Operation

The unit must be placed in a location ***free from vibrations*** and protected from direct sources of heat such as sunlight, heaters or furnaces. The ambient temperature should be between 10°C and 35°C (50–95°F).

Do not block the air intake openings on the bottom of the unit. Use the power cord provided to connect the OSMOMAT 030 from the power connector on the back of the unit to a power outlet. Make sure the unit's ground is enabled via the shockproof grounding.

If the power cord plug does not match the conventional power outlets in your location, you may substitute another power cord. It is essential, however, that the cable's green/yellow wire be connected to the safety grounding.

It is also important to ensure that the voltage indicated on the nameplate matches that of your electricity network. Incorrect voltage will cause the fuse in the power supply unit to blow.

The OSMOMAT 030 can now be switched on using the power switch on the back of the unit (next to the power connector). Five horizontal dashes appear on the digital display. Simultaneously, the SPONT.CRYS., RESULT and NO CRYST. control lamps will flash on and off for about two minutes. When the lamps go out, the OSMOMAT 030 is ready for measurements.

The waiting period of approximately two minutes is necessary for the formation of ice crystals at the upper cooling system. The waiting period can be interrupted by pressing any key.

Fill a measuring vessel with 50µl of sample solution (or 15µl for models with option M) and place it **securely** onto the measuring vessel holder (thermistor probe). (You will feel a slight resistance and hear a click.) The highly sensitive thermistor probe is now immersed in the sample solution.

Measuring vessels that are placed loosely or incorrectly will yield non-reproducible results.

Now press the measuring vessel holder down into the measuring position (noticeable resistance). The measuring vessel is immediately cooled by the lower cooling system.

The current temperature of the solution is shown on the digital display in degrees Celsius. The cooling process can be directly observed.

The moment the undercooling temperature is reached, crystallization is initiated automatically by the injection of ice crystals, and an acoustic signal sounds. The resulting ice formation causes the temperature to rise to the freezing point of the solution. A freezing plateau then forms that the thermistor probe records and the measurement system identifies, saves and shows on the digital display in osmol/kg or digits.

After the measurement process is finished—regardless of whether it was successful or produced an error message—and the elevator has been raised, the measurement system automatically switches to standby and is ready for the next measurement.

3.1 Safety and Handling Information

The cryoscopic osmometer OSMOMAT 030 is an electric laboratory measurement device. It should therefore be handled according to the safety provisions and precautions for electric measurement, control and laboratory equipment.

The unit must be adequately **disinfected** prior to **decommissioning**. Equipment must be **decommissioned** in accordance with local accident prevention guidelines.

The unit emits no harmful substances either in operation or while switched off.

Symbols on the unit and its nameplate correspond to the requirements of the following standards: DIN EN 61010-1, DIN EN 375 and DIN EN 980 (harmonized standard for medical devices according to § 3 no. 17 of the German Medical Device Law *MPG*).

3.2 Known Risks Associated with the Use of the OSMOMAT 030

In our experience using the Osmomat since 1979, we have not found it to present any direct hazards or risks to the user. Such hazards and risks cannot entirely be excluded for technical equipment, however.
These operating instructions help you gain a basic understanding of the design, the measurement principle, maintenance and servicing of the unit. Please pay special attention to chapter 7.7, *Replacing a Defective Initiation Needle.*

4 Calibrating the OSMOMAT 030

Before the total osmolality of sample solutions can be measured, the OSMOMAT 030 must be calibrated with distilled water and a calibration solution.

4.1 Calibrating the Zero Point with Distilled Water

Begin by pipetting 50 µl of distilled water (or 15µl for units with Option M) into a clean, dry measuring vessel.

⚠ ***There must be no visible air bubbles in the liquid!***

Next, place the measuring vessel securely onto the measuring vessel holder. (It should engage slightly.) Make sure the lid of the measuring vessel is pointing forward. The thermistor probe is now immersed in the water.
Press the ZERO key. The display shows 0.000 and the ZERO control lamp illuminates yellow. The measuring vessel holder is lowered and the cooling process begins. The display shows the current temperature.
After undercooling has occurred, the needle will automatically be submerged, initiating crystallization. The freezing point of distilled water will be achieved and recorded by the unit. The reading obtained by the unit is automatically adopted as the “zero value” and the value 0.000 is visible on the digital display.
If the built-in printer is switched on, “ZERO: 0.000” is printed out.

⚠ ***When calibrating, be aware that the thermistor probe may still be contaminated with sample residues from previous measurements.***

Following the zero point calibration, a control measurement with water should confirm the exact calibration. If necessary, a new calibration must be carried out.

⚠ ***Always use a new measuring vessel with fresh distilled water for each new measurement.***

4.2 Calibrating with a Calibration Solution

Begin by pipetting 50µl of calibration solution (or 15µl for units with Option M) into a clean, dry measuring vessel.

⚠ ***There must be no visible air bubbles in the liquid!***

Next, place the measuring vessel securely onto the measuring vessel holder. (It should engage slightly.) Make sure the lid of the measuring vessel is pointing forward. The thermistor probe is now immersed in the liquid.

Press the CAL key. The digital display shows the value 300 and the CAL control lamp illuminates yellow.

Pressing this key again toggles through the following values:

400[1]*, 500, 600, 700, 850, 900, 1200, 1500, 1800, 2000, 2500, 100, 200* and back to *300*.

It is thus possible to set the osmolality value of the calibration solution to be used.

Standard calibration solutions with an osmolality of 300mOsmol/kg and 850mOsmol/kg are provided in ampoules, but additional calibration solutions can be manufactured by the user. The corresponding NaCl concentrations can be found in the appendix to these operating instructions. This sets the value of the calibration solution used for calibration.

After the measuring vessel holder is lowered, the solution is undercooled and crystallization initiated. A reading is obtained that is automatically adopted as the calibration value according to the prior setting and output to the digital display.

If the built-in printer is switched on two values are printed out for a standard calibration solution. The measured one e.g. 0.298 and the “CAL- value: 0.300” (shown separately with an arrow).

⚠ ***When calibrating, be aware that the thermistor probe may still be contaminated with sample residues from previous measurements.***

Following calibration, a control measurement with the calibration solution or a solution of known osmolality should confirm the exact [2] setting. If necessary, a new calibration must be carried out.

⚠ ***Always use a new measuring vessel with fresh calibration solution for each new measurement.***

---

[1] Cf. chapter 8.4 Osmomat 030-3P

[2] Deviation: Sample volume of 50µl: <+/- 0.5%
Sample volume of 30µl: <+/- 1.0%
Sample volume of 15µl: <+/- 2.0%

5 Measuring a Sample Solution

After calibration or calibration confirmation, the unit is ready for sample measurements.

Since sample measurements must be carried out under the same conditions as the calibration, pipette 50 µl of the sample liquid (or 15µl for units with Option M) into a clean, dry measuring vessel.

It is essential that there be no air bubbles!

Place the measuring vessel containing the sample liquid securely onto the measuring vessel holder (thermistor probe). (It should engage slightly.) Make sure the lid of the measuring vessel is pointing forward. The thermistor probe is immersed in the sample liquid.

Before lowering the measuring vessel holder, press the SAMPLE key. (This step is not necessary if the SAMPLE control lamp is already illuminated.) Crystallization is automatically initiated once the sample liquid is undercooled. The temperature is shown on the display until the crystallization temperature of –7°C is reached.

The calculated freezing point temperature is recorded by the unit and, using the calibration value, converted into an osmolality value and output to the digital display.

The measurement result, together with a 4-digit sample number and the time of day, is printed out on the built-in printer (if switched on).

Use a soft paper towel to thoroughly clean the thermistor probe after each measurement. The sensor may also be cleaned beforehand with a cloth moistened with water.

5.1 Series Measurement

Pipette the various sample solutions into a corresponding number of measuring vessels and close their lids until you are ready to begin measurement.

Be sure to identify samples uniquely.

Erroneous measurements: Insufficiently sealed measuring vessels can lead to evaporation of the sample solution.

The samples are then measured sequentially, making full use of the high measuring speed of the OSMOMAT 030.

5.2 Repeating a Sample Measurement

To check reproducibility using repeat determinations, two clean and dry measuring vessels must be filled with the same sample solution. A repeat determination using just one sample is not possible, as the sample separates during measurement.

If, in exceptional circumstances, a repeat determination can only be run with one sample, the sample must be carefully thawed and mixed after the first measurement.

6 Error Messages and Troubleshooting

The following explains the error messages reported by the unit along with their possible causes and describes the proper use of measuring vessels.

6.1 Spontaneous Crystallization

The freezing point of a solution is measured by first undercooling the solution, without any ice formation, to a predefined temperature. Crystallization is then automatically initiated by injecting ice crystals. A portion of the solution's water content is crystallized out. The crystallization enthalpy causes an immediate rise in temperature up to the freezing point of the remaining, somewhat more highly concentrated solution. During the time in which both ice and solution are present, a freezing plateau then forms. Since ice is constantly forming through the ongoing gradual cooling of the sample, however, the concentration of the remaining solution increases steadily, leading to a steady increase of the osmolality and thereby inclining the freezing plateau to a specific degree. The OSMOMAT 030 obtains a reading for the total osmolality by calculating the temperature difference between the freezing point of the water and the reversal point detected while measuring the sample solution. The OSMOMAT 030 monitors the temperature changes during the undercooling phase. If crystallization begins prematurely, before the undercooling temperature of –7°C is reached, the error message "SPONT.CRYST." signals the error, and display of the erroneous reading—which in this case is too low—is suppressed.

6.2 Preventing False Readings Due to Spontaneous Crystallization

The main cause of spontaneous crystallization is the presence of seed crystals, which prevent undercooling to the proper temperature. Such seed crystals might be salt crystals, gas saturation or any pre-existing ice crystals. Seed crystals of this type can be easily eliminated by briefly heating the sample liquid close to its boiling point and subsequently cooling it. Seed crystals that cannot be eliminated in this manner may be removable through filtration. Salt crystal formation may result when cooling sample solutions contain certain salts whose low solubility or high concentration put them on the solubility threshold. These salt crystals then act as seed crystals. In such cases, adequate dilution may help, ***though precise results can no longer be expected***. (See also chapter 6.3.1, *Excessive Osmolality*.) Seed crystals can also adhere to the thermistor probe. Clean the sensor thoroughly using water and a soft paper towel to remove any seed crystals.

If the thermistor probe's glass bead has even a hairline scratch that cannot be removed, however, replace the sensor. Dirty measuring vessels (dust on the inside surface) can also cause such errors. See also chapter 7.6.
Measuring vessels that are re-used may eventually develop cracks in the plastic in which a fine liquid film can cause premature crystallization.

⚠ ***Measuring vessels are designed for single use only. Re-use of measuring vessels can lead to non-reproducible results.***

6.3 Late or Absent Crystallization

After the sample solution has been cooled to the proper temperature, crystallization is initiated automatically through the injection of ice crystals. There are two possible reasons for a failure of crystallization to occur:

6.3.1 Excessive Osmolality

Crystallization is initiated at –7°C.
The OSMOMAT 030 can measure solutions with a maximum osmolality of approximately ***3 osmols***, since this osmolal concentration yields a freezing point temperature of:

$$3 \times 1.858 = 5.574 \approx -5.6°C$$

If the freezing point is very close to the temperature at which crystallization is initiated, however, crystallization will not initiate despite the very effective method of initiating crystallization through the injection of ice crystals. This condition is further exacerbated if the solution exhibits a rising viscosity.
The only remedy in such cases is to adequately dilute the sample solution.
It must be taken into consideration, however, that the osmolality does not change in proportion to the dilution ratio, since the degree of electrolyte dissociation during dilution is different for each substance.
For routine measurements—quality inspections, for example—corresponding relative measurement results from diluted samples can be used as a basis for evaluation.

6.3.2 Injection with Ice Crystals Does Not Work

If no crystallization occurs during the crystallization-initiating phase despite the sounding of the acoustic signal and even though the sample liquid does not exhibit excessive osmolality, there are various possible causes. (See also chapter 6.4, *Classification of Malfunctions by Component Group*.)

1. The stainless steel needle that transports the ice crystals is not moving from its upper to lower position. A mechanical problem is preventing the movement of the needle.

Remedy: Unscrew the thermistor probe. The needle can then be straightened ***(caution—risk of injury!)***, repositioned and checked for mechanical maneuverability. The movement of the needle can be tested by pressing the MOTOR button on the back of the unit.

2. The ice crystals at the tip of the stainless steel needle are not reaching the undercooled liquid sample despite the lack of any mechanical problem with the movement of the needle. The iced-covered tip of the stainless steel needle passes through a bore above the measuring vessel during the crystallization-initiating phase. This bore may contain a drop of water or be very dirty. The drop of water may be the result of ice crystals falling from the upper cooling system.

Remedy: Use the Pasteur pipette included with the accessories together with a long tube as a bellows to blow debris from the bore. First remove the measuring vessel and hold a paper towel underneath the thermistor probe. The bore can first be rinsed using a spray bottle of water to clean out sample residues, which can rub off and accumulate on the interior surface over time. The unit does not need to be switched off for this cleaning process, so measurement is only briefly interrupted.

3. No ice forms in the upper cooling system because the humidity is too low or the unit was operated too quickly after having been switched on.

Remedy: Do not run the initial measurement until at least two minutes have elapsed after the unit was switched on. If the air humidity is very low (for example, in heated or air-conditioned rooms), it may be necessary to open the cover of the upper cooling system.

6.4 Classification of Malfunctions by Component Group

The following presents an overview of the individual component groups, identifying the function of each component, its potential malfunctions, the effects of the malfunctions on the measurement system, the possible causes of the malfunctions and the procedure for correcting each malfunction.
Calibration cannot help minimize damage in the case of malfunction. It is also of no consequence whether these malfunctions occur during calibration or sample measurement.
Some errors can be remedied directly by the user or an in-house medical equipment technician; others require return of the unit to the manufacturer.

Component and *Function*	Malfunction	Effect	Possible Cause	Procedure
Elevator guide *Manually lowers the sample into the lower cooling system*	Sluggish (noisy)		Mechanical wear due to ball bearing abrasion	Lubricate the track, e.g. with silicone spray or graphite
	Jams	Error message or incorrect reading	Blockage from foreign substances	Remove foreign substance
Lower cooling system *Cools the sample*	No cooling, measurement takes too long, measurement terminates	No reading Error message	Corrosion	Use fine sandpaper to clean the cooling clamp
		Display -.- - -	Photosensor for controlling lower cooling system is defective or misaligned	Make sure the photosensor is working and is positioned properly; replace if necessary
		Incorrect reading	Misaligned lower cooling system	Use the adjustment tool to align the lower cooling system
			Peltier element defective	Replace the lower cooling system

Table 1: Malfunction of the elevator track/lower cooling system component group

Component and *Function*	Malfunction	Effect	Possible Cause	Procedure
Upper cooling system *Nucleation*	No cooling or no ice crystals at the upper cooling system	Error message and no reading	Peltier element ruined, e.g. through deposits from liquids	Replace upper cooling system
			Corrosion	Clean the cooling nipple using a fine wire brush (fiberglass pin) or fine sandpaper
	Insufficient ice accumulation on the bar of the needle	No crystallization No reading Error message	Misaligned upper cooling system	Align the cooling system
			Bar of needle too short or too long	Align the needle bar or check for proper length
	Incomplete rotation of the motor disc (with initiation needle)	No crystallization No reading Error message	Photosensor for motor control defective or misaligned	Make sure the photosensor is working and is positioned properly
			Motor disc loose	Tighten the motor disc

Table 2: Malfunction of the upper cooling system component group

Component and *Function*	Malfunction	Effect	Possible Cause	Procedure
EPROM	Defective	Calibration and measurement impossible or results not verifiable	Aging, External electric shock, Excessive electromagnetic irradiation	Check electromagnetic compatibility of equipment operating near osmometer Check system load of power grid Have medical equipment technician or Gonotec replace EPROM
Thermistor probe *Analysis*	Measuring vessel fits loosely on the thermistor probe	Incorrect reading	Incorrect measuring vessel Incorrect placement of measuring vessel The thermistor probe's measuring vessel receptacle is damaged	Use measuring vessels recommended by Gonotec Place measuring vessel securely on sensor (until you hear a click) Replace the thermistor probe
	Defective	Display shows lines but no numbers _._ _ _	Thermistor probe bead broken off or defective	Replace the thermistor probe
	When lowered into the lower cooling system, the thermistor probe moves outside the center of the solution	Incorrect reading	Misaligned thermistor probe Incorrect measuring vessel	Use the adjustment tool to align the thermistor probe and/or lower cooling system

Table 3: Malfunction of the EPROM/thermistor probe component group

Component and *Function*	Malfunction	Effect	Possible Cause	Procedure
Ventilator *Cools the entire system*	Doesn't work (not moving)	Measurement process too slow No reading Error message	Ventilator blocked by foreign object (e.g. measurement vessel)	Check unit for foreign objects
		Destruction of lower cooling system	Ventilator defective	Replace ventilator
	Emits strange noises	Destruction of electronics (e.g. lower cooling system)	Ventilator impaired by foreign object or is no longer running within its bearing	Check unit for foreign objects and/or replace ventilator immediately
Display *Displays readings*	Numbers or decimal points flicker or disappear		Loose contact in wiring to mainboard	Check the wiring between the display and the mainboard
	Nonsensical readings (Option D)		Date on printer changed (manually or automatically)	Repeat measurement and press the Sample or Zero key, depending on the next work step
			Display defective	Replace display

Table 4: Malfunction of the ventilator/display component group

Component and *Function*	Malfunction	Effect	Possible Cause	Procedure
Initiation needle *Crystallization*	No/few ice crystals transported	Error message: No crystallization	Needle too long or too short	Bring needle to proper length
			Needle not deburred at tip (e.g. after re-installation)	Debur tip of needle
			Needle bent	Straighten or replace needle
	Needle does not move	Error message: No crystallization	Bar of needle disengaged from motor or stuck firmly in place	Check upper cooling system component group
Rear of unit/power switch *Power supply*	Fuses in power switch blow out when unit is switched on	The following parts may be damaged: - Mainboard - Transformer	Unit voltage setting does not match power grid voltage	Check setting for proper unit voltage of 110 V or 230 V. Check for that fuse plug is seated properly. Insert new fuses.
	Unit does not turn on		No external power supply	Check cables leading to unit
			Fuses are burnt out	Replace fuses If another cause is found, the unit must be sent to customer service

Table 5: Malfunction of the initiation needle/power switch component group

Component and *Function*	Malfunction	Effect	Possible Cause	Procedure
Printer *Outputs readings*	Prints no results or nonsensical results	Reading not printed out	Date in printer changed	Repeat measurement and press the Sample or Zero key, depending on the next work step
			Cable break	Check the printer's cable connections
	Prints no results		No paper or ribbon needs replacing	Replace paper or ribbon
	Does not print		Printer switched off	Switch printer on
			Wiring to mainboard interrupted	Check wiring
			Defective	Replace printer

Table 6: Malfunction of the printer component group

7 Servicing the OSMOMAT 030

7.1 Requirements of the Medical Devices Operator Ordinance

The regulatory scope of Germany's Medical Devices Operator Ordinance includes the maintenance and servicing of medical devices. Sections **2 (Special Regulations for Active Medical Devices)** and **3 (Medical Devices with Measurement Functions)** regulate the safety and measurement checks to be performed on medical devices.
These checks are mandatory for devices listed in *Annexes 1 and 2 of the Medical Devices Operator Ordinance*.

7.2 Safety Checks (§ 6 of Medical Devices Operator Ordinance)

The OSMOMAT 030 is not listed in Annex 1 of the Medical Devices Operator Ordinance. Public authorities do not require the unit to undergo safety checks.

Safety checks should be conducted by the on-site safety coordinator in accordance with relevant accident prevention guidelines.

7.3 Measurement Checks (§ 11 of Medical Devices Operator Ordinance)

The Osmomat 030 is not listed in Annex 2 of the Medical Devices Operator Ordinance. No measurement checks are stipulated by the Ordinance.
The user should perform the following checks, however:

- ***Calibration of the unit with a standardized osmometry calibration solution***
- ***Comparative measurements with OSMOREF® 290 or aqueous solutions of known osmolality***
- ***Logging of measurement readings and any evaluation results***

The frequency of such checks should follow local quality assurance guidelines.

7.4 Internal Quality Control of the OSMOMAT 030

A microcontroller monitors the unit's functions based on the program flow. The failure of individual functional groups in the unit results in a malfunction that either reports an error message or shuts down the unit. Standardized calibration and reference solutions and an adjustment tool are used to check the internal quality control mechanism.

7.5 Aligning the Thermistor Probe

Good reproducibility relies on a few key elements. To ensure optimal reproducibility, the thermistor probe must be exactly in the center of the measuring vessel during measurement. This is especially important to remember when a defective thermistor probe is replaced.

7.6 Replacing a Defective Thermistor Probe

Before replacing a defective sensor, ***unplug the unit from the power supply! Risk of electric shock!***

Step 1

Raise the cover of the upper cooling system (Figure 7: Elevator cover). Two screws can be seen. They must be removed in order to remove the entire cover.

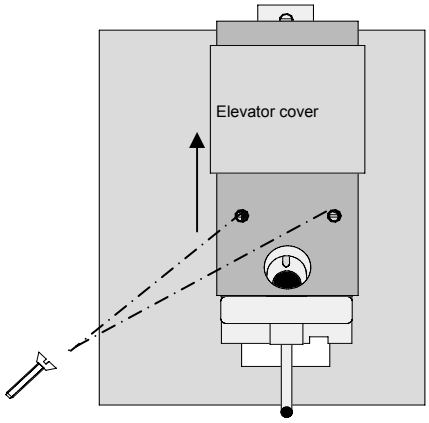


Figure 4: Elevator cover

Step 2

Two more screws are now visible. Remove these also (Figure 5: **Mounting plate**).

Step 3

Next, remove the plug (black/brown) from the connector (white). Now you can remove the thermistor and mounting plate from the initiation needle. The initiation needle will slide out of the guide tube and pull the protective tubing along with it.

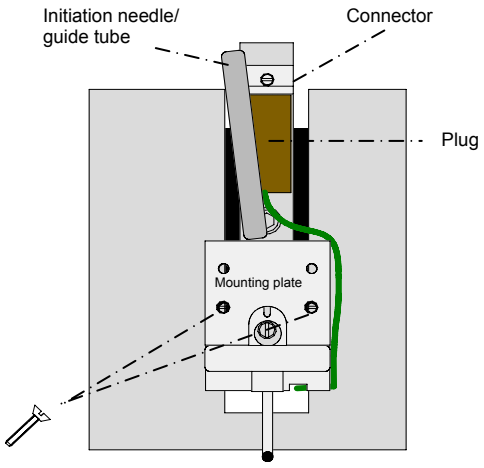


Figure 5: Mounting plate

Warning: Risk of injury from the tip of the needle!

Step 4

Now unscrew the thermistor from the mounting plate and replace it with a new one (Figure 6: **Thermistor with mounting plate**).

Step 5

Re-assemble in reverse sequence by pushing the protective tubing over the initiation needle and attaching the mounting plate using the two screws.

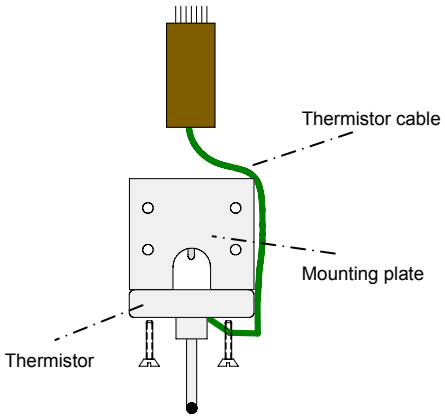


Figure 6: Thermistor with mounting plate

Next, insert the plug of the connector cable into the connector and guide the thermistor cable into the groove along the side. The re-attached thermistor must then be aligned.

Step 6 Aligning the thermistor probe

⚠ ***Alignment of the thermistor probe and the lower cooling system is of critical importance for reproducibility of the OSMOMAT 030 cryoscopic osmometer readings. A special tool, included in the standard accessories, is required to adjust the thermistor probe.***

The purpose of the adjustment is align the center axis of the cooling clamp with the thermistor axis (see Figure 7: **Thermistor probe adjustment along X-axis** and Figure 8: **Thermistor probe adjustment along Y-axis**). Adjustment proceeds as follows:

a) Place the adjustment tool into the lower cooling system, checking for a *snug fit*.

b) **Carefully** lower the thermistor probe. The thermistor probe must fit exactly into the opening in the adjustment tool. If this is not the case, the thermistor probe or the lower cooling system must be re-aligned.

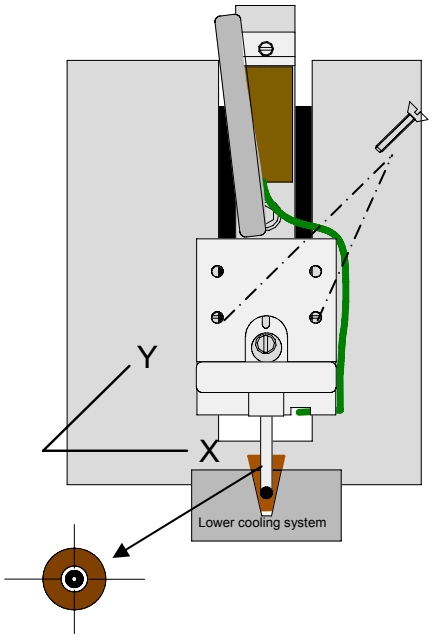


Figure 7: Thermistor probe adjustment along X-axis

If the thermistor probe is off-center along its **X-axis** (right or left), loosen its screws and re-adjust it (Figure 7: **Thermistor probe adjustment along X-axis**). **Repeat the process until the bead at the tip of the thermistor probe is exactly in the center of the adjustment tool** (see Figure 7: **Thermistor probe adjustment along X-axis**), then carefully tighten the retaining screws. Remove the adjustment tool and re-attach the upper cooling system cover with its two screws.

c) If the thermistor probe is off-center along its **Y-axis**, the lower cooling system must be aligned. To align the lower cooling system, unscrew the lower face plate and re-align the lower cooling system to the center of the thermistor probe by loosening the grub screws (hex socket screws) and mounting screws (hex socket or slotted screws, depending on the model) on the bottom of the housing (Figure 8: **Thermistor probe adjustment along Y-axis**).

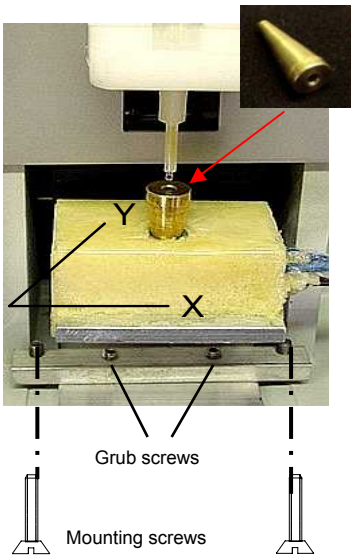


Figure 8: Thermistor probe adjustment along Y-axis

7.7 Replacing a Defective Initiation Needle

There are various reasons for which it may become necessary to work on the needle bar or even replace the initiation needle. See **Table 2: Malfunction of the cooling system component group** and **Table 5: Malfunction of the switch component group**

Repairs to the initiation needle must be performed by a **medical device technician**; it is not enough simply to be skilled in handling equipment!

Before working on the initiation needle, please ensure the following:

Unit power supply is disconnected!
Risk of electric shock!

Unit has been ***decontaminated—especially the initiation needle!***
Risk of injury from the tip of the needle!

In the event of injury from the tip of the needle, always consult a doctor to check whether any infection with a pathogen occurred.

Step 1

Unscrew the upper face plate, elevator cover and mounting plate (see **Figure 2: Front view of the OSMOMAT 030**; see the description in chapter 7.5; Figure 4: **Elevator cover** and Figure 5: **Mounting plate**). Detach the needle bar from the motor swipt (Figure 9: **Replacing an initiation needle**).

Attach a new needle bar with protective tubing to the motor swipe.

Please note:

a. The needle must be carefully aligned. Bend it into place with your hand if necessary.

b. After the needle bar has been tightened, it must be able to move freely on the sleeve bearing.

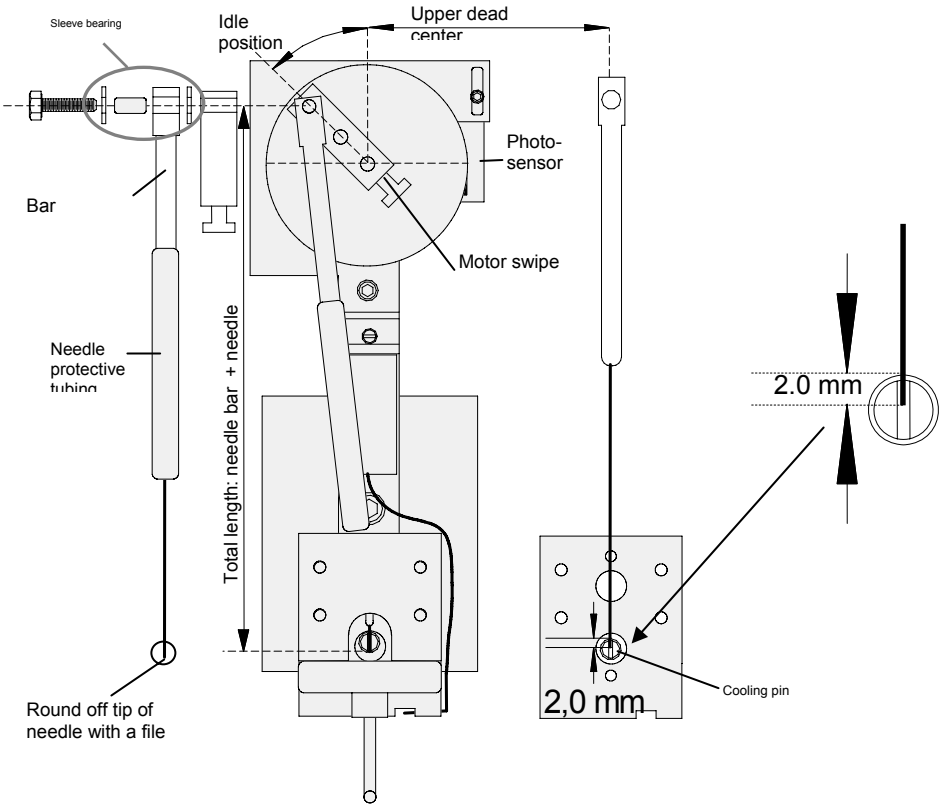


Figure 9: Replacing an initiation needle

Step 2

a. Manually move the motor swipe to the upper dead center position.

b. Use a pair of pliers to adjust the needle to the proper length (end of needle approximately 2 mm under the upper edge of the cooling pin).

c. Carefully round off the cutting edge with a file. (In the idle position of the motor swipe, the end of the needle must not extend below the lower edge of the cooling pin. If necessary, adjust the reflex photosensor by moving it up or down (after first loosening the hex socket screws).

Step 3

Align the thermistor probe; see chapter 7.5.

Step 4

Re-assemble the unit and run a check by pressing the MOTOR button on the back of the unit.

Note: Inititiaon needle material: stainless steel, cold-hammered quality, diameter 0.6mm

7.8 Replacing a Defective Mains Fuse

Before beginning work, ***unplug the main power supply! Risk of electric shock!***

To replace the fuses, use a small screwdriver to remove the fuse holder on the back of the unit. The two fuses can now be replaced. The unit has two-phase protection. Use the following fuses:

230V power supply: 0.5A slow/LAG
115V power supply: 1A slow/LAG

One set of fuses is included with the standard accessories.

Make sure to re-insert the fuse holder in its original position.

*The labels **"115"** and **"230"** are printed on either side of the fuse holder. The fuse holder must be inserted such that **the correct voltage indication (see nameplate,** Figure 1**) is located underneath the power cord connector. A small arrow ▲ (***Figure 10: **Power switch***) points to the voltage setting. The picture here shows a setting for 230V.*

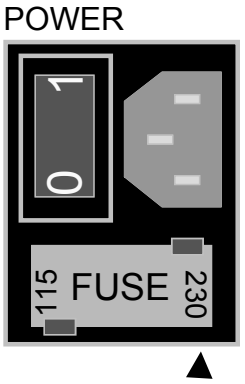


Figure 10: Power switch

7.9 Using the Correct Measuring Vessel

One critical factor affecting the service life and precision of the measurement system is the use of the correct measuring vessel.

7.9.1 Intended Use

*The measuring vessels are intended for **single use only**. Re-use of the measuring vessels can result in non-verifiable readings or even a **destruction of the measurement system**.*

We are unaware of any reactions between the sample solution and measuring vessel (in osmometry). However, we advise against using the measuring vessels for other purposes.

For information on the material properties, please refer to the product safety data sheet **MPM-30.9.0010.pdf**.

7.9.2 Specification

The conic shape of the measuring vessel matches that of the lower cooling system. This ensures a **secure fit**, a high standard of **centricity** for the measuring vessel in the lower cooling system and **consistent immersion depth** of the measuring tip in the sample.

When the measuring vessel is placed on the thermistor probe, a soft clicking sound is heard and there is a tangible resistance. If this is not the case and the measuring vessel does not fit securely, it is possible you are using an improper measuring vessel and the measurement results may not be verifiable.

Re-used measuring vessels also exhibit these characteristics. This is because their openings are dilated when they are placed on the sensor.

7.9.3 Forfeiture of Measurement System Warranty

Destruction of the measurement system through use of improper measuring vessels, even during the warranty period, shall result in forfeiture of the warranty claim of repair or replacement of the measurement system.

8 Options

8.1 OSMOMAT 030-D with Built-In Printer

The OSMOMAT 030-D is equipped with a dot matrix printer. The printer uses normal paper and an ink ribbon cartridge. The printer paper an the continuous loop ribbon cartridge are consumables and must eventually be replaced. The OSMOMAT 030-D is fully operable even if the printer is off. The results can be seen on the digital display after each measurement.

8.1.1 Design and Function of the OSMOMAT 030-D

8.1.2 Overview of Display and Connectors

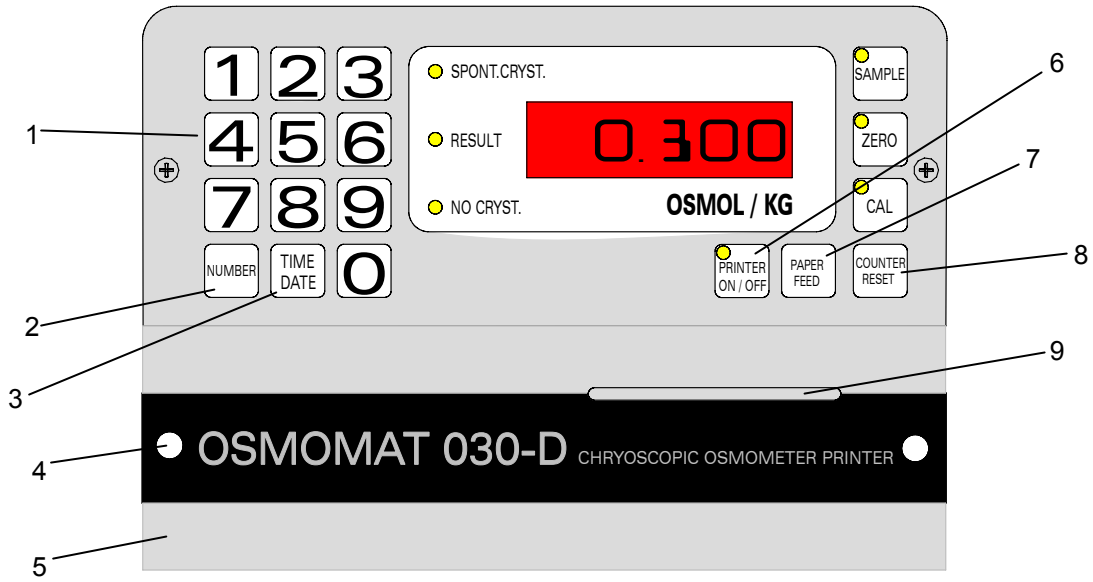


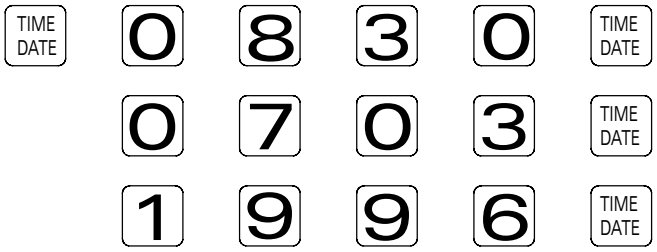
Figure 11: OSMOMAT 030-D display

1 - Numerical keypad
2 - Key for entering sample number
3 - Key for setting time and date
4 - Thumbscrews
5 - Plexiglas shield
6 - Printer ON/OFF switch
7 - Paper feed
8 - Counter reset
9 - Paper output with tear-off edge

8.1.3 Setting the Time and Date

The time, day, month and year are set using the *TIME/DATE* key (3) (Figure 11: **OSMOMAT 030-D display**) and the *numerical keypad.*

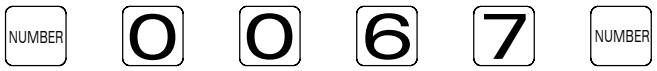
To set 08:30 on 7 March 1996, for example, input the following on the keypad:



Pressing the *TIME/DATE* key at the end stores the time and date.

The sample number is set using the *NUMBER* key (2) (Figure 11: **OSMOMAT 030-D display**) and the *numerical keypad.*

Setting the sample number 67, for example, requires the following keypad entry.



The next reading will then be numbered 67.

Note: *The sample number and the sequential number are identical. The next measurement will thus be numbered 68, the one after that 69, and so forth.*

8.1.4 Operating the Printer

Press the *PRINTER ON/OFF* key once to switch on the printer. If the OSMOMAT 030-D is on, the yellow LED illuminates.

When the printer is switched on for the first time, the log header is automatically printed out. The measurement results are automatically printed out if the *RESULT* LED illuminates and the results are saved.

A sequential number is printed out along with the measurement results. Press the *COUNTER RESET* key to print out a new log header and reset the numbering to 1.

Mismeasurements that do not produce a result on the digital display and during which the LED for spontaneous crystallization or no crystallization illuminate are not counted. A plain-text explanation for the mismeasurement is printed out.

A tear-off edge allows the printout to be torn off cleanly.

8.1.5 Replacing the Printer Paper

A. Unscrew the two *thumbscrews* (4) to remove the *plexiglas shield* (5) (Figure 11: **OSMOMAT 030-D display**).

B. Lightly press the lower left portion of the printer to open it (Figure 12: **Opening the printer**).

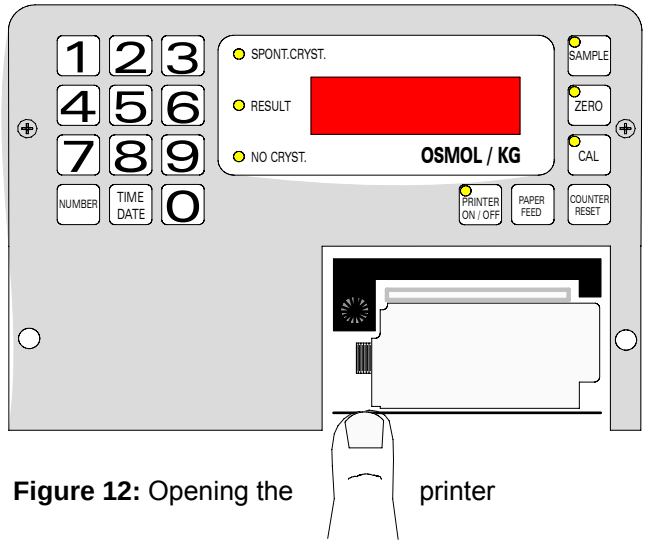


Figure 12: Opening the printer

C. Remove the empty paper spool from the paper compartment (Figure 15: **Printer with paper roll**). Remove any remaining paper not by pulling it out backwards but by pressing the *PAPER FEED* (7) key to advance it through the opening.

D. Insert a new roll of paper. (Refer to *Consumables* in the appendix for supply information.) Switch on the OSMOMAT 030-D and the printer. Cut the paper cleanly and feed the end into the paper output slot from above. Press the *PAPER FEED* key (7) (Figure 11: **OSMOMAT 030-D display**) to advance the paper through the opening, leaving about 1 inch / 2 cm protruding. Make sure the roll is fed in the correct direction (Figure 15: **Printer with paper roll** and Figure 13: **Correct feed direction for paper roll**).

Place the roll in the paper compartment and close the printer. Thread the paper through the slot of the plexiglas shield (6) (Figure 11: **OSMOMAT 030-D display**) and re-attach the shield. Before starting the next measurements, press the *COUNTER RESET* key (8) (Figure 11: **OSMOMAT 030-D display**) to print the header.

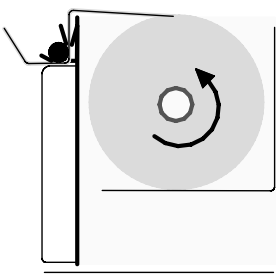


Figure 13: Correct feed direction for paper roll

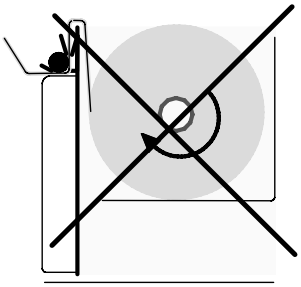


Figure 14: Incorrect feed direction for paper roll

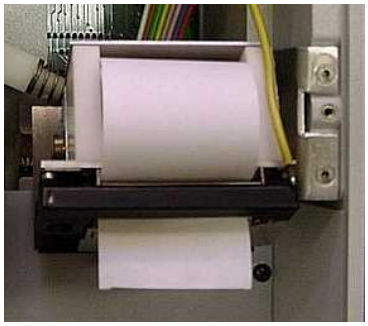


Figure 15: Printer with paper roll

8.1.6 Replacing the Ribbon Cartridge

The ribbon cartridge must be replaced when the printout no longer has sufficient contrast. The OSMOMAT 030-D can be on or off while the ribbon is replaced.

A. Tear off any paper protruding from the slot before replacing the ribbon.

B. Remove the two *thumbscrews* (4) (Figure 11: **OSMOMAT 030-D display**) and take off the *plexiglas shield* (5) (Figure 11: **OSMOMAT 030-D display**).

C. Press lightly on the right-hand side of the used ribbon cartridge to remove it (Figure 16: **Replacing the ribbon**).

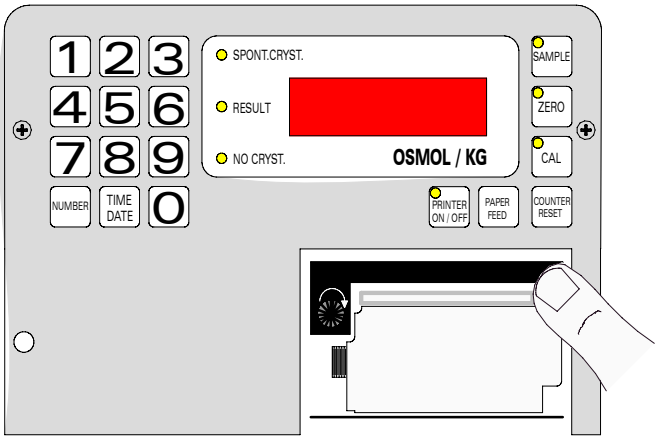


Figure 16: Replacing the ribbon

D. Remove the new ribbon cartridge from its packaging. (Refer to *Consumables* in the appendix for supply information.)

E. Use your index finger to twist the adjuster knob clockwise and tighten the ribbon.

F. Insert the cartridge into the printer. The end of the paper must be between the ribbon and the cartridge.

G. Twist the knob again to tighten the ribbon.

H. Re-attach the Plexiglas shield.

8.2 OSMOMAT 030-M with 15µl Sample Volume

The measurement system of the OSMOMAT 030-M is set for a microsample volume of 15µl. The corresponding special thermistor probe is labeled 15µl.
The OSMOMAT 030-M can also be used to measure sample volumes up to 50µl.

Please note the following important restrictions and operational guidelines:

Reproducibility is not affected by using a larger sample volume. *It remains unchanged at <±2.0%*

Especially careful preparation is necessary due to the minimal sample volume. In particular: there must be no air bubbles and the measuring vessel must be seated correctly.

Do not replace the thermistor probe with a 50µl thermistor probe. This will destroy the measurement system.

8.2.1 Specifications

Display	4.5 digits
Measuring range	0 to approximately 3000 mOsmol/kg
Resolution	1 mOsmol/kg or 1 mOsmol/digit across the entire measuring range
Reproducibility	<±2.0%

8.3 OSMOMAT 030-RS with Digital, Serial Data Output RS 232C

8.3.1 Overview of Connector Components

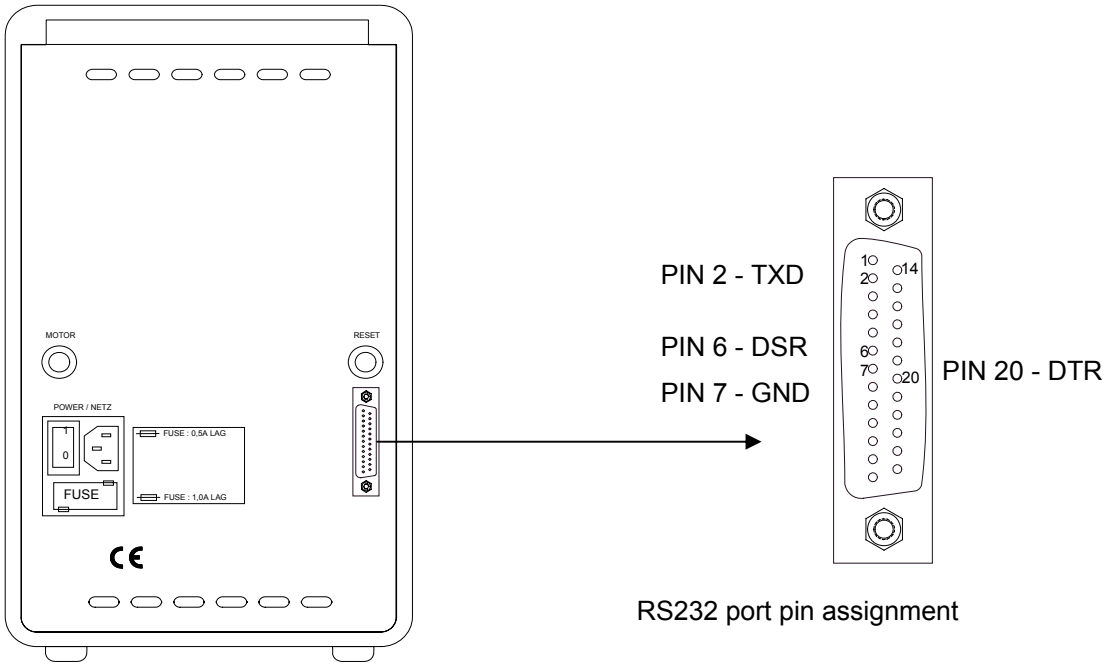


Figure 17: RS232 interface with pin assignment

8.3.2 Specifications

Baud rate:
Transmission speed: 1200 bits/s.

Data format:
1 start bit,
8 data bits and
2 stop bits are transmitted.

Signals:

TXD -	Transmit Data (output)
Idle level	–3V >> U >> –7.5V
Active level	+3V << U << +7.5V
DTR -	Data Terminal Ready (output)

This signal indicates the transmission readiness of the OSMOMAT 030, i.e. it becomes active before a telegram is sent.

Idle level	–3V >> U >> –7.5V
Active level	+3V << U << +7.5V
DSR -	Dataset Ready (input)

This signal can prevent transmission of a telegram. The OSMOMAT starts transmitting only after DSR becomes active. The user does not need to activate this signal, since it is equipped with an internal 15 k-Ohm 'pull-up' resistance.

Idle level	–3V >> U >> –15V
Active level	+3V << U << +15V

8.3.2.1 Telegram Format

A telegram is sent after the completion of each measurement. Data is transmitted in the ASCII format. Depending on whether the *Option D (dot matrix printer)* is activated, one of two telegram formats is sent.

8.3.2.1.1 Printer is Off or Does Not Exist

If the printer option is not installed, it is not possible to set the sample number, date and time. Only the measurement reading is transmitted.

8.3.2.1.2 Printer is On

If the printer is switched on, the sample number, date and time are output in addition to the measurement reading.

8.3.2.1.3 Output Format for Faulty Measurements

In the event of faulty measurements, the cause of the error is output in plain text:

SPONTANEOUS CRYSTALLIZATION

NO CRYSTALLIZATION

8.3.3 Communication Software

We recommend using our OSMOTERM software for easy data transmission to PC and data acquisition that is optimized for the equipment. In principle, any other terminal software can be used, but the data format will have to be adjusted.

8.4 OSMOMAT 030-A with Analog Data Output

8.4.1 Overview of Display and Connectors

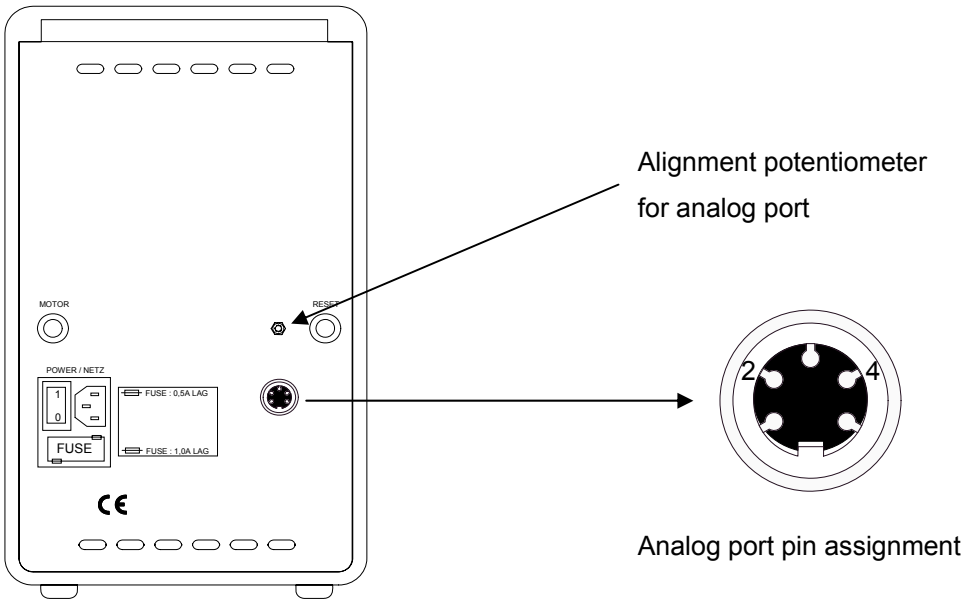


Figure 18: Analog interface with pin assignment

8.4.2 Specifications

Output voltage:	1 mV = 1 mOsmol
Maximum output:	+/- 14 V
Minimal load resistance:	R = 4.7 kOhm

The output voltage is independent of the storage function of the *RESULT* display.

The recorder cable that is included is intended only for the analog output (*output port pin 2 and pin 4,* Figure 18: **Analog interface with pin assignment**).

The output voltage of the analog output can be aligned with the *alignment potentiometer* for older flatbed recorders.

8.5 OSMOMAT 030-3P with Three-Point Calibration

To improve linearity across a broader measuring range, it makes sense to calibrate at three points.
Our standard model OSMOMAT 030 with a reproducibility of +/- 0.5% has linearity of +/- 1% in a measuring range from 0 to approximately 700 mOsmol/kg.
Above 700mOsmol/kg up to about 2000mOsmol/kg, the linearity varies by +/- 2%. Measurements over 2000mOsmol/kg show a variance of +/- 3%. (Basis: two-point calibration at 0 and 300mOsmol/kg).
To extend the range with a linearity variance of +/- 1%, Option 3P allows calibration at one more point above 0 and 300mOsmol/kg (e.g. 850mOsmol/kg). The result is a correspondingly wider range with a linearity of +/-1%.

8.5.1 Overview of Display

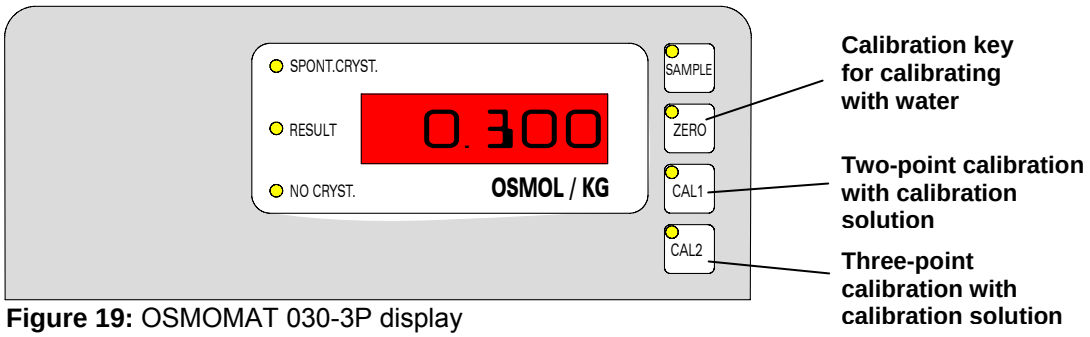


Figure 19: OSMOMAT 030-3P display

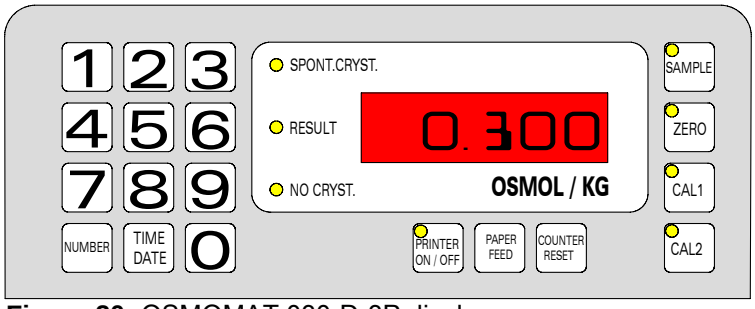


Figure 20: OSMOMAT 030-D-3P display

8.5.2 Calibration Modes

The OSMOMAT 030-3P can be calibrated in two different modes:

1. If you calibrate at just 0 and 300mOsmol/kg, the linearity corresponds to that of the OSMOMAT 030 as described above.
2. If you calibrate at 0 and, for example, 300 and 850mOsmol/kg, you achieve results with a linearity variance of +/- 1% across a wider range.

When the OSMOMAT 030-3P is switched on, it displays the mode in which it was last calibrated.

1. LED on the **'**CAL**1'** key **illuminates** (Figure 19: **OSMOMAT 030-3P display**) → Standard mode (**2-point calibration**)
2. LED on the **'**CAL**2'** key **illuminates** (Figure 19: **OSMOMAT 030-3P display**) → **3-point calibration mode**

8.5.3 Performing a Three-Point Calibration

1. Zero point
    1. Press the **'Zero'** key.
    2. Fill the measuring vessel with 50µl* of distilled water.
    3. Run measurement → Value is automatically calibrated by unit.
    4. Control: Run another measurement with distilled water.

2. 1st calibration point of 300mOsmol/kg
    1. Press the **'CAL1'** key.
    2. Fill the measuring vessel with 50µl* of Gonotec calibration standard 300mOsmol/kg.
    3. Run measurement → Value is automatically calibrated by unit.
    4. Control: Run another measurement with Gonotec calibration standard 300mOsmol/kg.

3. 2nd calibration point of 850 mOsmol/kg
    1. Press the **'CAL2'** key.
    2. Fill the measuring vessel with 50µl* Gonotec calibration standard 850mOsmol/kg.
    3. Run measurement → Value is automatically calibrated by unit.
    4. Control: Run another measurement with Gonotec calibration standard 850mOsmol/kg.

* For Option M, run these measurements with a volume of 15µl.

8.5.4 Errors During Calibration

It is possible that error may occur during calibration. **The individual steps should always be controlled as described above.**

The OSMOMAT 030-3P recognizes if the calibration solutions are interchanged or the same calibration solution is used at two different calibration points and displays an error message ('E.EEE'). The measured value is rejected and the unit must be reset. Reset the unit either by pressing the RESET button on the back of the unit (Figure 3: Rear view of the Osmomat 030

or by switching the unit off and then immediately back on again (the ON/OFF switch is also located on the back of the unit). The OSMOMAT is then in the same state as before the faulty calibration attempt.

The OSMOMAT 030-3P is unable to recognize slightly faulty calibration solutions, such as those subjected to open storage. Calibration of such solutions is faulty and leads to incorrect results. The inevitable result is miscalibration of the unit and thus faulty measurement results with your samples.

8.5.5 Other Calibration Points

We can guarantee the reproducibility of our OSMOMAT 030-3P using Gonotec calibration standards, because our calibration standards are manufactured under the most stringent guidelines and undergo continual checks.
Of course, you may use calibration standards of other manufacturers or create your own, but we cannot make any claims for the expected measurements.

The following calibration points are possible:

1. Zero → always calibrated with distilled water
2. CAL1: 100, 200, 300, 500, 700, 850, 900, 1200, 1500, 1800, 2000, 2500
3. CAL2: 300, 500, 700, 850, 900, 1200, 1500, 1800, 2000, 2500, 3000

For CAL2: the minimum gap to CAL1 lies with the next but one calibration point. For example:
CAL1 = 100 mOsmol/kg: for CAL2 all calibration points from 300 mOsmol/kg onwards are possible.
CAL1 = 200 mOsmol/kg: for CAL2 all calibration points from 500 mOsmol/kg onwards are possible.
CAL1 = 300 mOsmol/kg: for CAL2 all calibration points from 700 mOsmol/kg onwards are possible.
…
CAL1 = 2000 mOsmol/kg: for CAL2 is 3000 mOsmol/kg possible.

8.6 Further Options

Most options can be combined, yielding the following potential constellations:

- OSMOMAT 030-A-D
- OSMOMAT 030-A-D-RS
- OSMOMAT 030-A-RS

with or without Option M.

Restriction

Option 3P may be combined with Options D, RS and M but **not** with **Option A**!

9 NaCl Calibration Solutions for Osmometry

9.1 GONOTEC Calibration- and Reference Material

Classification of the IVD

The calibration- and reference material manufactured by Gonotec is a non-invasive in-vitro diagnostic product according to EEC Directive 93/42 (Medical Devices Law). It is intended for use in osmometry by qualified personnel in calibrating and/or controlling the osmometer. The calibration- and reference material must be used in accordance with equipment specifications.
The calibration- and reference material is not named in Annex II, list A or B, of the Directive 98/79 for in-vitro diagnostics. Compliance is declared per Annex III. Number 6 of Annex II is disregarded, as the calibration- and reference material's intended use does not include personal use.

EC Compliance Statement—Calibration- and Reference Material

Gonotec GmbH
Eisenacher Straße 56
D- 10823 Berlin, Germany

We hereby declare that the calibration standard for Osmomat 010/030/auto (300 and 850mOsmol/kg $NaCl/H_2O$) and the reference solution OSMOREF® 290 mOsmol/kg complies with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the calibration- and reference material acknowledges this.

Date: 09.11.2004

Signature of managing director:

Provisions of Certification

CE compliance requires that the calibration- and reference material be used in the manner described in this manual and/or in the package insert. Any departure from the specifications or independent modifications of the calibration- and reference material without the express consent of Gonotec GmbH may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

9.2 Restrictions on Use of the Calibration- and Reference Material

- The calibration- and reference material may not be used to clean contact lenses or the like.
- The calibration- and reference material may not be used in human injections or infusions, neither in its pure form nor in mixtures with human bodily fluid samples.
- The calibration- and reference material may not be used to calibrate or create samples of chemical or biological origin for administration into the human body.

9.3 Composition

Calibration standard 300, 850, 2000 mOsmol/kg and OSMOREF® 290 mOsmol/kg NaCl/H_2O

		300 mOsmol	850 mOsmol	2000 mOsmol	290 mOsmol
Sodium chloride	Ph.Eur./USP	9.448 kg	27.178 kg	63.960 kg	9.124 kg
Water for injection purposes as bulk	Ph.Eur./USP	ad 1000 l	ad 1000 l	ad 1000 l	ad 1000 l

For precise concentrations, see the analysis certificate on the package insert of each batch.

9.4 Safety and Handling Information

The calibration- and reference material is not a dangerous substance according to EC Directive 67/548/EEC.	
Poison class (Switzerland):	F (no poison class)
German water hazard class (WGK):	nwg (not hazardous to water)
Storage class (German association of chemical industries, VCI):	10-13 (miscellaneous liquids and solids)
Disposing of materials:	according to GLP / institution's practice / country, state and local requirements

Attention: The calibration- and reference material is a **chemical**. Observe all relevant **precautions** and **regulations** (do not swallow, do not taste, always wear gloves, etc.)

Container: clear glass OPC ampoules

Nominal volume: 1 ml

The ampoules have a breaking ring with a breaking ring color (blue dot). The ampoule can be opened manually by breaking it off at this point. Follow all safety precautions for the handling of glass (splintering, breakage, etc.).

9.5 Storage and Shelf Life

When stored unopened at 5°C to 45°C, the calibration- and reference material has a shelf life up to the expiration date indicated on the packaging.
Do not use the calibration- and reference material after its expiration date!

Once the ampoule has been opened, the calibration- and reference material shelf life is:
up to ½ hour at + 22°C.

A strong variance in calibration readings (e.g. increasing osmolality) are an indication that the shelf life has elapsed.

9.6 Use of Other Calibration Solutions

Osmolality	Sodium chloride concentration	Freezing point depression
Milliosmol / kg H_2O	g NaCl / kg H_2O	in C°
100	3.088	0.1858
200	6.26	0.3716
300	**9.463**	**0.5574**
400	12.685	0.7432
500	15.916	0.9290
600	19.148	1.1148
700	22.38	1.3006
750	23.98	1.395
850	**27.178**	**1.5793**
1200	38.37	2.23
1800	57.56	3.35
2000	**63.960**	**3.7.16**
2500	79.97	4.65

Table 7: NaCl solutions for osmometry based on Geigy scientific tables, 8th edition

Appendix

Consumables

Article no.	Article	Packaging unit/qty
30.9.0010	Measuring vessel for OSMOMAT 030	1,000
30.9.0020	Calibration standard 300 mOsmol/kg (ampoules of 1 ml each)	50
30.9.0850	Calibration standard 850 mOsmol/kg (ampoules of 1 ml each)	10
30.9.2000	Calibration standard 2000 mOsmol/kg (ampoules of 1 ml each)	10
30.9.0290	Reference solution OSMOREF® 290 mOsmol/kg (ampoules of 1 ml each)	10
30.9.1010	Rolls of printer paper for OSMOMAT 030-D	8
30.9.1020	Endless ink ribbon cassette for OSMOMAT 030-D	1

Accessories and Replacement Parts

Article no.	Article	Packaging unit/qty
30.3.0010	Thermistor probe for OSMOMAT 030 (50µl sample volume)	1
30.3.2010	Thermistor probe for OSMOMAT 030-M (15µl sample volume)	1
30.9.0030	Pasteur pipette (bellow), 10 pc.	1
30.6.0020	Initiation needle	1
20.9.0160	Data cable for RS 232 interface OSMOMAT 030/050	1
30.2.0030	Adjustment tool	1
20.9.0100	Power cord, 2 meters	1
00.9.0104	Package with 10 fine-wire fuses, 0.5 A slow, 220 V	1
00.9.0106	Package with 10 fine-wire fuses, 1.0 A slow, 110 V	1
20.9.0120	Connector cable for recorder	1

Classification of the IVD

The Osmomat® 030 cryoscopic osmometer manufactured by Gonotec is a non-invasive in-vitro diagnostic product according to EEC Directive 93/42 (Medical Devices Law). The Osmomat® 030 cryoscopic osmometer is not named in Annex II, list A or B, of the Directive 98/79/EEC for in-vitro diagnostics. Compliance is declared per Annex III. Number 6 of Annex II is disregarded, as the unit's intended use does not include personal use.

EC Compliance Statement—OSMOMAT® 030

Gonotec GmbH
Eisenacher Straße 56
D- 10823 Berlin, Germany

We hereby declare that the OSMOMAT® 030 cryoscopic osmometer and its options comply with Directive 98/79/EEC. Compliance is declared per Annex III of the Directive. The CE mark on the unit acknowledges this.

Date: 01.10.2004

Signature of managing director:

Provisions of Certification

CE compliance requires that the unit be installed and operated in the manner described in this manual. Any departure from the specifications or independent modifications of the unit without the express consent of Gonotec GmbH may result in a violation of CE requirements. Such actions invalidate the compliance statement and transfer responsibility to the originator of said actions.

Limited Warranty

Gonotec product	Duration of limited warranty
Software	90 days
Thermistor probe	180 days
Osmometer	1 year

A. Extension of the Limited Warranty

1. Gonotec warrants the end user that Gonotec products shall be free from manufacturing and material defects for the above periods of validity from the purchase date. The end user must provide proof of the purchase date.
2. For software products, Gonotec's limited warranty applies only to the non-execution of programming instructions. Gonotec does not warrant that the operation of a product will proceed without errors or interruptions.
3. Gonotec's limited warranty applies only to defects that arise during normal operation of the product. It does not apply under the following conditions:
   d. Inadequate servicing or improper modification;
   e. Use of software, interfaces, print media or accessories not supported or supplied by Gonotec; or
   f. Use of the equipment in a manner not covered by the product specifications.
4. For Gonotec osmometers, the use of measuring vessels of manufacturers other than those of the measuring vessels supplied by Gonotec does not void the customer's warranty claims or any customer support contracts between Gonotec and the customer.
   If, however, the use of measuring vessels from third-party providers or the cleaning of recycled measuring vessels results in malfunctions or damage to the osmometer or thermistor probe, Gonotec shall assess the normal fees for the time and material required to repair such malfunctions or damage.
5. If Gonotec is notified within the warranty period of a defect in a software product, in media or in a thermistor probe and if the Gonotec warranty applies to the defect, Gonotec shall replace the defective product. If Gonotec is notified within the warranty period of a defect in a hardware product and if the Gonotec warranty applies to the defect, Gonotec shall repair or replace the defective product at its discretion.
6. If Gonotec is unable to repair or replace a defective product to which the Gonotec warranty applies, Gonotec shall refund the purchase price of the product within a reasonable period following notification of the respective defect.
7. Gonotec is not obligated to repair or replace a product or refund its purchase price until the customer returns the defective product to Gonotec.
8. Replacement products may be new or almost new, as long as their functionality is at least that of the replaced product.
9. The Gonotec limited warranty is applicable in all countries in which Gonotec sells the applicable product. The following countries and regions are excepted: All countries outside the EU. In these countries, the warranty is only valid in the country in which the product was purchased. Contracts for additional warranty services, such as on-site service, may be available from an authorized Gonotec sales partner.

B. Limitation of the Warranty

1. TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL ASSUME ANY ADDITIONAL WARRANTY SERVICES OR ACCEPT ANY OTHER CONDITIONS, EXPRESS OR IMPLIED, WITH REGARD TO THE GONOTEC PRODUCTS.

C. Limitations of Liability

1. To the extent permissible under the applicable local laws, the legal remedies named here shall be the sole and exclusive legal remedies available to the customer.
2. TO THE EXTENT PERMISSIBLE UNDER THE APPLICABLE LOCAL LAWS AND WITH THE EXCEPTION OF THE OBLIGATIONS EXPRESSLY NAMED HERE, NEITHER GONOTEC NOR ITS SUPPLIERS SHALL BE LIABLE FOR DIRECT OR INDIRECT, SPECIFIC, INCIDENTAL OR CONSEQUENTIAL LOSSES, WHETHER BASED ON A CONTRACT, A TORTIOUS ACT OR ANOTHER LEGAL THEORY, AND NOTWITHSTANDING PRIOR NOTIFICATION OF THE POSSIBILITY OF SUCH A LOSS.

D. Respective Jurisdiction

1 This warranty statement guarantees the customer certain legal claims. The customer may have other legal claims that go beyond those outlined here. Such claims vary by state in the US, by province in Canada and by nation elsewhere in the world.

2. Elements of this warranty statement that conflict with local laws can be regarded as amended to comply with the applicable laws. For this reason, certain warranty exclusions and restrictions outlined here may be of no relevance to the customer. In some states of the US, in some Canadian provinces and in some countries outside North America, for example, the following national laws apply:
   a. Exclusion of the fact that the warranty exclusions and restrictions named here restrict the legal rights of a customer (for example: Great Britain)
   b. Restriction of the possibilities for manufacturers to enforce such warranty exclusions and restrictions
   c. Granting of additional warranty claims for the customer, fixing of the validity period for implied warranty services that the manufacturer may not exclude, or nonadmission of restrictions relating to the validity period for implied warranty services
3. THE FOLLOWING APPLIES TO CONSUMER TRANSACTIONS IN AUSTRALIA AND NEW ZEALAND: THE CONDITIONS OF THIS WARRANTY STATEMENT NEITHER EXCLUDE LEGAL RIGHTS APPLICABLE TO THE SALE OF GONOTEC PRODUCTS TO SUCH CUSTOMERS NOR REPRESENT A RESTRICTION OR AMENDMENT OF SUCH RIGHTS, BUT INSTEAD REPRESENT A SUPPLEMENT TO THESE RIGHTS, EXCEPT TO THE EXTENT PERMISSIBLE UNDER THE LAW.

Returning Parts for Warranty Repair or Credit

All products returned for repair or credit must be prepared as follows:

1. Call or write to request a free return order for equipment that is being returned to us for warranty repair or credit.
   You may also request a return order for equipment that is being returned for non-warranty repair, but you will be liable for the cost of the return order.

2. Clean and disinfect the equipment before returning it to us. We will charge a processing fee for cleaning and disinfecting contaminated equipment. Equipment that is greatly contaminated will be returned at the customer's expense.

3. Insert the protective packaging material (notched foam cushion) between the thermistor probe and the elevator.

4. Enclose written information explaining the reason for returning the equipment.

5. If the equipment is being returned for credit, you must include all accessories (power cord, software discs, manuals, etc.).

6. Return the equipment in its original packaging. If you no longer have the original packaging, you may purchase a replacement from Gonotec.

Before Calling Gonotec

Note: When calling Gonotec, have your unit's serial number ready. The serial number helps our service technicians to more quickly record the unit and determine a procedure.

If possible, switch on the unit before calling Gonotec's technical service. Use a telephone that is close to the unit. You may be asked to provide detailed information while running operations or apply other troubleshooting methods that can only be performed on the unit itself. Ensure that you have the equipment documentation handy.

Warning: Before undertaking any work on the equipment, read the safety notices in the appropriate chapters of this manual.

Tel.: +49 (030) 7809588-0

freecall (Germany only!):
0800-7846027

OSMOMAT 030 Upgrade Options

The following useful options enhance the practical value of the standard model and can be factory-installed for an additional price:

Option D: Built-in dot matrix normal-paper printer for automatic recording of the measurement results with user-defined four-digit sample numbering, date and time. The OSMOMAT 030-D ensures reliable recording of the measurement results, together with and easily distinguishable from the sample numbering, and increases the speed of series measurements.

Option A: Analog port for continuous recording of the temperature development with a compensating recorder.

Option RS: Digital, serial data output RS 232 C for connecting the OSMOMAT 030-RS to a computer.

Option M: The OSMOMAT 030-M is programmed for a microsample volume of 15µl. Reproducibility is <±2%. This option is recommended if only small sample volumes are available. If the OSMOMAT 030-M is used to measure sample volumes up to 50µl, the reproducibility remains at <±2%.

Option 3-P: Calibration at three points. Besides water, two other calibration points are possible.

The above options can be combined in almost any way. Only the options A and 3P cannot be combined with each other.

Specifications of OSMOMAT 030

(Standard model)

Sample volume:	50µl to 30µl
Duration of measurement	Approx. 1 minute
Reproducibility:	< ±0.5% (50µl) < ±1.0% (30µl)
Measurement display:	4.5 digits
Measuring range:	Up to approximately 3000mOsmol/kg
Resolution:	1 mOsmol/kg across the entire measuring range
Crystallization resolution	Using the ice crystal-laced tip of an automatically controlled stainless steel needle
Cooling:	Using two independent peltier cooling systems with heat dissipation through the air
Lower cooling system:	Temperature controlled electronically, consistency better than ±0.1°C
Ambient temperature:	10°C to 35°C
Power connection:	220V (± 30V), 50/60 Hz, 120VA, Special models: 110V, 100V
Dimensions:	220 x 205 x 360 mm
Weight:	Approximately 7 kg

(Options)

Option D:	Alphanumeric dot matrix printer, 5x7 matrix, date, time of each measurement
Number of digits:	4-digit programmable sample number 4-digit measurement results
Paper:	Normal paper, 43 mm wide
Paper feed:	Automatic or manual
Printer function:	Manual on/off key
Error message:	Printout in plain text
Option A:	Analog output via DIN standard socket, 5-pin
Output voltage:	1 mV/mOsmol
Option RS:	Data output (serial), standard RS 232 C interface
Baud rate:	1200 bps
Data format:	1 start bit, 8 data bits, 2 stop bits (no parity check)
Data line:	TXD
Control line:	DTR, DSR
Connector plug:	Canon, 25-pin
Option M:	15 µl sample volume
Reproducibility:	< ±2.0%
Option 3-P:	Special version for 3-point calibration